K113383

JUN 26 2012

XtraFix External Fixation System Line Additions
510(k) Summary

Device Manufacturer:	ExtraOrtho, Inc. 8275 Tournament Drive, Suite 160 Memphis, TN 38125
Submission Date:	November 16, 2011
Contact Person:	Brian Austin Tel: 1-901-748-2581 Fax: 1-901-748-2583
Proprietary Name:	XtraFix External Fixation System Line Additions
Common Name:	External Fixation Frame Components
Classification regulation:	888.3030 Single/multiple component metallic bone fixation appliances and accessories, 888.3040 Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Product Codes:	KTT and JDW/ Orthopedics/87

Device Description and Intended Use:
The XtraFix External Fixation System includes various elements designed to build a fixator construct. The line additions include new clamps and half pins.

The XtraFix External Fixation System is indicated for use in construction of an external fixation frame for treatment of long bone (femur, tibia, foot and humerus) and pelvic fractures that require external fixation. Specifically, the system is intended for:

- Stabilization of open or closed fractures, typically in the context of polytrauma or where open or alternative closed treatment is undesirable or otherwise contraindicated;
- Arthrodesis and osteotomies with associated soft tissue problems;
- Stabilization of limbs after removal of total joint arthroplasty for infection or other failure;
- Stabilization of non-unions; and
- Intraoperative temporary stabilization tool to assist with indirect reduction.

Predicate Devices:
The XtraFix External Fixation System Line Additions are similar to several predicates including the following:

- XtraFix External Fixation System (K091258 and K111155);

K113383

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510(k) Summary

- Synthes Large External Fixation Clamps- MR S (K031428); and
- Smith & Nephew Jet-X Unilateral Fixator (K994143).

Technological Characteristics

The principles of operation of the XtraFix External Fixation System Line Additions are the same as for the predicates. The system was characterized and evaluated according to the requirements outlined in ASTM F1541-02 (2007), Standard Specification and Test Methods for External Fixation Devices and the FDA Reviewers Guidance Checklist for Orthopedic External Fixation Devices. The XtraFix External Fixation System Line Additions were also characterized and evaluated according to the requirements outlined in FDA Guidance document, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment." Testing confirmed the devices can be used in an MR environment under predetermined conditions. Therefore, the term "MR Conditional" can be used to describe the system in accordance with the guidance document.

Substantial Equivalence Information:

The XtraFix External Fixation System is similar to legally marketed devices listed previously in that they share similar indications for use and incorporate similar technological characteristics. All evaluations determined that the XtraFix External Fixation System is substantially equivalent to the predicate devices.

p. 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 26 2012

Extraortho, Inc.
c/o Marcos Velez-Duran
President of MSquared Associates, Inc.
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K113383
Trade/Device Name: XtraFix External Fixator System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: April 6, 2012
Received: April 9, 2012

Dear Mr. Velez-Duran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113383

Indications for Use Statement

510(k) Number: To be assigned

Device Name: XtraFix External Fixation System

Indications for Use: The XtraFix External Fixation System is indicated for use in construction of an external fixation frame for treatment of long bone (femur, tibia, foot and humerus) and pelvic fractures that require external fixation. Specifically, the system is intended for:

- Stabilization of open or closed fractures, typically in the context of polytrauma or where open or alternative closed treatment is undesirable or otherwise contraindicated;
- Arthrodesis and osteotomies with associated soft tissue problems;
- Stabilization of limbs after removal of total joint arthroplasty for infection or other failure;
- Stabilization of non-unions; and
- Intraoperative temporary stabilization tool to assist with indirect reduction.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113383